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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,604	06/29/2001	Robert A. Hallowitz	BIOT1-11	6514

7590 02/26/2007

Theranostech, Inc.
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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/893,604	HALLOWITZ ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 08 December, 2006. Claims 1-7 and 9-17 have been canceled without prejudice or disclaimer. Claim 8 is the only pending claim.

35 U.S.C. § 120

Acknowledgement is hereby made of applicants' request for priority under 35 U.S.C. § 120 as set forth in the communications filed 29 October, 2004, and 08 December, 2006. Applicants are reminded that if the benefit of a prior-filed application under 35 U.S.C. § 120 is desired, a specific reference to the prior-filed application in compliance with 37 C.F.R. § 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. § 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. If the instant application is a utility or plant application filed under 35 U.S.C. § 111(a) on or after November 29, 2000, **the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application** or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. § 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. § 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 C.F.R. §

1.78(a)(2)(ii) and (a)(5)(ii). **This time period is not extendable and a failure to submit the reference required by 35 U.S.C. § 119(e) and/or § 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. § 119(e), § 120, § 121 and § 365(c).** A benefit claim filed **after** the required time period may be accepted if it is accompanied by a grantable **petition** to accept an unintentionally delayed benefit claim under 35 U.S.C. § 119(e), § 120, § 121 and § 365(c). **The petition must be accompanied by (1) the reference required by 35 U.S.C. § 120 or § 119(e) and 37 C.F.R. § 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 C.F.R. § 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 C.F.R. § 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional.** The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. If the reference to the prior application was previously submitted within the time period set forth in 37 C.F.R. § 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 C.F.R. § 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 C.F.R. § 1.78(a) and the surcharge under 37 C.F.R. § 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 C.F.R. § 1.78(a) by filling an amendment to the first sentence(s) of the specification or an ADS. See M.P.E.P. § 201.11.

Since applicants failed to properly establish their claim to

priority within four months from the actual filing date of the instant application, a petition, surcharge, and statement are required as set forth *supra*.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

The previous rejection of claims 1-3, 5-7, 9, and 10 under 35 U.S.C. § 103(a) as being unpatentable over Daniel *et al.* (1993), is moot in view of applicants' amendment.

The previous rejection of claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Daniel *et al.* (1993) in view of Cummings *et*

al. (1999), is moot in view of applicants' amendment.

The previous rejection of claims 11, 12, 14, 15, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Daniel *et al.* (1993), is moot in view of applicants' amendment.

The previous rejection of claim 13 under 35 U.S.C. § 103(a) as being unpatentable over Daniel *et al.* (1993) in view of Cummings *et al.* (1999), is moot in view of applicants' amendment.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over King and Hallowitz (1998) in view of King and Hallowitz (2001). As previously set forth, King and Hallowitz (1998) disclose a method for detecting cell-surface gp120 that employs a first anti-gp120 labeled antibody and a second anti-gp120 antibody attached to a magnetic particle. The antibodies are added to an aqueous sample under conditions that facilitate binding, immune complexes are isolated using a magnetic field, and the number of lymphocytes expressing cell-surface gp120 is ascertained. This teaching does not disclose the utilization of a second anti-label antibody that is attached to a magnetic particle. However, King and Hallowitz (2001) provide an assay for the detection of virally infected cells that employs anti-label antibodies attached to magnetic particles. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to employ the immunological reagents of King and Hallowitz (2001) in the cell-surface gp120 assay of King and Hallowitz (1998) since this would provide a rapid and facile means for detecting virally infected cells. Absent evidence to the contrary, one of ordinary skill in the art would have been motivated to use any one of a number of art-recognized immunological formats to detect the item of interest. Thus, both

sufficient motivation and a reasonable expectation of success were present in the prior art. Applicants traverse and submit that the teachings relied upon are not applicable as prior art given the priority claims under 35 U.S.C. § 120. Applicants are reminded that they have failed to perfect the priority claim under this statute for the reasons set forth *supra*. Accordingly, the effective filing date of the instant application is 30 June, 2000, based upon provisional application 60/215,075. King and Hallowitz (1998) has an effective filing date of 15 October, 1996, and is applicable as prior art under this statute. King and Hallowitz (2001) has an effective filing date of 15 October, 1997, and is also applicable as prior art under this statute.

No claims are allowed. Applicants' representative is advised that the examiner conducted an allowability conference with his supervisor and it was determined that no claims were allowable. Applicants' representative is invited to contact the examiner if they have any further questions or concerns pertaining to this office action.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply

expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

20 February, 2007